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Subcommittee on Commercial and Administrative Law
House of Representatives

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on
"The Administrative Law, Process, and Procedure Project"

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss this Subcommittee's bipartisan "Administrative Law, Process, and Procedure Project" and our work during the past two years related to that project. As my colleague Mort Rosenberg mentioned, an underlying theme in many of the comments and recommendations received related to those projects has been that the newly reauthorized Administrative Conference of the United States (ACUS) should be funded and tasked with addressing many of these kinds of topics. The projects also yielded numerous issues that Congress may want to address. My testimony today will focus on three elements of the administrative law project — presidential review of agency rulemaking, the utility of regulatory analysis and accountability requirements, and the role of science in the regulatory process — and will highlight some of the issues identified for ACUS or for Congress.

Presidential Review of Agency Rulemaking

At the September 11, 2006, symposium on "Presidential, Congressional, and Judicial Control of Rulemaking" that CRS sponsored for this Subcommittee, there was a great deal of discussion about whether Congress or the courts or the President actually controls agency rulemaking behavior.[1] At the conclusion of the day, the consensus seemed to be that, on a

[1] The transcripts of this symposium are available online at the website for the Center for the Study (continued...)

day-to-day basis, the President has far more control than either of the other branches. During the past 25 years, the epicenter of presidential control has been the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget. Although created by the Paperwork Reduction Act of 1980 and periodically tasked by Congress with other statutory responsibilities, OIRA is located within the Executive Office of the President and reviews hundreds of agency regulations each year before they are published to ensure that the President's policies are implemented. In a sense, therefore, OIRA embodies the tension between presidential and congressional control.

I moderated a panel at the September 11 symposium on "Presidential Review of Rulemaking: Reagan to Bush II." One of the participants on that panel was Sally Katzen, currently a professor of law at George Mason University who was administrator of OIRA from 1993 to 1998 during the Clinton Administration. As Professor Katzen pointed out, all presidents since President Nixon have called for some form of centralized review in order to, as she put it, "get their hands around agency rulemaking." The genesis of the current form of centralized presidential review is traceable to President Reagan's Executive Order 12291 in 1981, which tasked the newly-created OIRA with reviewing all agency rules except those from independent regulatory commissions — several thousand per year.[2] In 1985, President Reagan extended OIRA's influence over rulemaking even further by issuing Executive Order 12498, which required covered agencies to submit a "regulatory program" to OMB each year listing all of their significant regulatory actions underway or planned.[3] As a result, any rule submitted to OIRA for review that had not been previously identified could be returned to the agency for "reconsideration."

The expansion of OIRA's authority in the rulemaking process via these executive orders was highly controversial. Some voiced concerns that OIRA's role violated the constitutional separation of powers and could affect public participation and the timeliness of agencies' rules.[4] Some believed that OIRA's new authority displaced the discretionary authority of agency decision makers in violation of congressional delegations of rulemaking authority, and that the President exceeded his authority in issuing the executive orders. Others indicated that OIRA did not have the technical expertise needed to instruct agencies about the content of their rules. Still other concerns focused what was viewed as a lack of transparency of the review process. Professor Katzen said that during the Reagan era and, to a certain extent, during the Bush I era, OIRA was "a big black hole" where regulations went in and the public didn't know what happened. She also said OIRA was generally known as a group of "lean, mean junkyard dogs" who required agencies to make the changes that it wanted, and emphasized reducing regulatory costs over all other goals.

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[1] (...continued)
of Rulemaking at American University [http://www.american.edu/rulemaking/news/index.htm].

[2] Executive Order 12291, "Federal Regulation," 46 *Federal Register* 13193, Feb. 19, 1981.

[3] Executive Order 12498, "Regulatory Planning Process," 50 *Federal Register* 1036, Jan. 8, 1985.

[4] U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Role of OMB in Regulation*, 97th Cong., 1st sess., June 18, 1981 (Washington: GPO, 1981). See also Morton Rosenberg, "Beyond the Limits of Executive Power: Presidential Control of Agency Rulemaking Under Executive Order 12291," *Michigan Law Review*, vol. 80 (Dec. 1981), pp. 193-247.

When President Clinton took office and Sally Katzen became head of OIRA in 1993, she said they wrote Executive Order 12866 to make several basic changes in the presidential review process.[5] For example, under this executive order, OIRA only reviews "significant" rules from the covered agencies, reducing the number of rules reviewed from several thousand to about 600 per year. The new executive order also improved the transparency of OIRA's reviews by, for example, requiring agencies to disclose the changes made as a result of OIRA's review. Other changes included reaffirming the "primacy" of the agencies in the rulemaking process (since, she argued, they possess the subject matter expertise and experience) and recognizing that non-quantifiable costs and benefits are essential to consider. In essence, Professor Katzen said, OIRA adopted a more cooperative and friendly approach to the agencies than had been the case during the Reagan and first Bush Administrations.

When the current President Bush took office in 2001, and particularly after John Graham became OIRA administrator in July of that year, OIRA's role in presidential review changed again — even though the pertinent executive order stayed the same. OIRA's role as "gatekeeper" or watchdog returned, and with it came an increased emphasis on economic analysis and an increase in letters from OIRA returning rules to the agencies for their "reconsideration." OIRA also ventured into several new areas, publishing bulletins in the last three years on peer review practices, agencies' use of guidance documents, and risk assessment procedures. OIRA became somewhat more transparent during John Graham's nearly five-year tenure, disclosing meetings with outside parties about rules whenever they occurred and publishing on the Office's website the status of all rules under review. However, OIRA still contends that the changes that it recommends to agencies before the formal review process begins (when OIRA says it has its greatest impact) should not be disclosed to the public. Also, although OIRA reveals its meetings with outside parties, the lists provided sometimes make it difficult to know what rule is being discussed or who the outside parties actually represent.

In the last several years, several scholars have attempted to assess the actual impact that OIRA has on rules.[6] While some of these studies are interesting and quite good, to really understand OIRA's effects, researchers must go rule-by-rule and examine the evidence provided in rulemaking dockets. One such study that the General Accounting Office (GAO, now Government Accountability Office) completed three years ago revealed that OIRA frequently suggested only minor changes to rules, but had a much more significant impact on certain types of rules — most notably rules submitted to OIRA from the Environmental Protection Agency's (EPA) air and water programs and the Federal Aviation Administration.[7] For example, at OIRA's recommendation, EPA removed manganese from a list of hazardous wastes, deleted certain types of engines from coverage of a rule setting emissions standards, and delayed the compliance dates for two other types of emissions.

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[5] Executive Order 12866, "Regulatory Planning and Review," *58 Federal Register* 51735, Oct. 4, 1993. To view a copy of this order, see [http://www.whitehouse.gov/omb/inforeg/eo12866.pdf].

[6] See, for example, Steven Croley, "White House Review of Agency Rulemaking: An Empirical Investigation," *University of Chicago Law Review*, vol. 70 (Summer 2003), pp. 821-885; Scott Farrow, *Improving Regulatory Performance: Does Executive Office Oversight Matter?* (Pittsburgh: Carnegie Mellon University, July 26, 2000).

[7] U.S. General Accounting Office, *Rulemaking: OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews*, GAO-03-929, Sept.2003.

GAO also reported that, in several of these cases, OIRA recommended what business interest groups had suggested during their previous meetings with OIRA.

Although the nature of OIRA's review has clearly changed substantially during the past 25 years, there is little if any continued questioning of the legality of centralized presidential review. Many rulemaking agencies recognize that OIRA review can add value because it brings a different perspective to the rulemaking process and can, by its very presence, prevent bad ideas from becoming rules. However, many public interest groups do question whether centralized review is a good idea, arguing that OIRA review has usually been a "one-way rachet" that weakens, not strengthens, rules; that it is still highly secretive and delays the issuance of rules; and that OIRA reviewers have caused agencies to issue rules that are inconsistent with their statutory mandates. Business groups, on the other hand, have argued that OIRA has not been assertive enough, and that agencies still control the rulemaking process to an unwarranted degree.

Unresolved Issues. Several issues regarding presidential review remain unresolved. For example:

- Should Congress codify presidential review of agency rulemaking? If so, how detailed should that codification be? For example, it might simply authorize the President to issue an executive order on this issue (thereby giving future Presidents the flexibility to change its provisions), with certain other requirements for transparency and limits on delay. Or should a codification spell out in detail the process by which Presidents should review rules before they are published? What are the policy implications of codification?

- Should independent regulatory agencies' rules be subject to presidential review? Or would presidential review adversely affect the independence intended for these agencies?

- What rules should govern OMB's contacts with outside parties during the presidential review process? For example, should OMB be allowed to meet with regulated entities outside of the period when agencies are not permitted to do so? Should OMB be required to disclose to the public not only that such a meeting occurred, but also a summary of what was said (as some agencies are required to do) in order to provide an administrative record for any subsequent changes?

- Are improvements in review transparency currently needed (either administratively or by statute)? For example, should agencies or OIRA be required to disclose substantive changes made to rules during "informal" reviews (when OMB says it can have its greatest effect)?

- Does OIRA have the legal authority to promulgate requirements or even guidelines regarding agencies' use of peer reviews, risk assessments, or guidance documents?

- Is presidential review of rules cost effective? Is there any way to objectively measure the benefits that OIRA review provides?

- Should OIRA's funding and staffing be increased, decreased, or stay the same? If increased, is there evidence that doing so would yield substantial returns on investment?

Regulatory Analysis and Accountability Requirements

Regulatory analysis and accountability requirements vary considerably with regard to their sources, their content, and their effectiveness. Some of these requirements are traceable to the presidential reviews that I just discussed, while others have their roots in statute. The "grandfather" of these requirements, and the foundation for most of them, is the Administrative Procedure Act (APA) of 1946 (5 U.S.C. 551 *et seq.*) which generally requires that agencies publish their proposed rules in the *Federal Register*, receive and consider comments on the proposed rules, and then publish a final rule stating its basis and purpose. Because my colleague T.J. Halstead is covering the APA and public participation issues in his testimony, I will only note that the word "generally" in my previous sentence is important here. A 1998 GAO study indicated that about half of all final rules were published without an opportunity for prior public comment, with agencies often invoking the "good cause" exception that allows them to avoid publishing a proposed rule for comment if the agency concludes it is "impracticable, unnecessary, or not in the public interest."[8] While many of these final rules were on relatively minor issues, some were "significant" rules under Executive Order 12866, and some had at least a $100 million impact on the economy.

Between 1946 and 1980, Congress established dozens of federal agencies and programs designed to improve the environment, make workplaces safer, and protect consumers. Subsequently, an array of federal economic, environmental, and social regulations were put in place that affected many of the decisions made by American businesses. Strong concerns then began to be raised about whether the benefits that these regulations and regulatory agencies were attempting to achieve were worth the costs associated with compliance. Concerns were also being raised about the cumulative effects of all federal regulations on individual businesses, and the effects that federal rules were having on particular segments of the economy (e.g., small businesses), and on other levels of government.

Congressional Initiatives. Since 1980, Congress has reacted to these concerns by establishing analytical and/or accountability requirements as part of the rulemaking process. These requirements have a variety of purposes, including the protection of certain interests from unnecessary regulatory burden, increased control over rulemaking agencies, and ensuring that the rules issued focus on issues of real public concern in as efficient and effective manner possible. Statutory initiatives imposing these requirements include the (1) the Regulatory Flexibility Act (RFA) of 1980 (5 U.S.C. 601-612), (2) the Paperwork Reduction Act (PRA) of 1980 (44 U.S.C. 3501-3520), (3) the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1532-1538), and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). Although these regulatory requirements clearly have had an effect on agency actions, many of them do not appear to have been as effective as their advocates had hoped.

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[8] U.S. General Accounting Office, *Federal Rulemaking: Agencies Often Issued Final Actions Without Proposed Rules*, GAO/GGD-98-126, Aug. 31, 1998.

For example, the Regulatory Flexibility Act requires federal agencies to assess the impact of their forthcoming regulations on "small entities" (e.g., small businesses and small governments), and requires that analysis to describe, among other things, (1) the reasons why the regulatory action is being considered; (2) the small entities to which the proposed rule will apply and, where feasible, an estimate of their number; (3) the projected reporting, recordkeeping, and other compliance requirements of the proposed rule; and (4) any significant alternatives to the rule that would accomplish the statutory objectives while minimizing the impact on small entities. However, the RFA's analytical requirements are not triggered if the head of the issuing agency certifies that the proposed rule would not have a "significant economic impact on a substantial number of small entities." The RFA does not define "significant economic impact" or "substantial number of small entities," thereby giving federal agencies substantial discretion regarding when the act's analytical requirements are triggered. A 2000 GAO study determined that EPA certified virtually all of its rules as not needing an RFA analysis, even rules that impose thousands of dollars of compliance cost on thousands of small entities.[9] Also, the RFA's analytical requirements do not apply to final rules for which the agency does not publish a proposed rule, and agencies do not have to consider the cumulative impact of their rules in making analytical determinations under the act. Finally, the courts have said that the act does not require the analysis with regard to indirect effects on small entities.[10] GAO has examined the implementation of the RFA several times within the past 10 to 15 years, and a recurring theme in GAO's reports is the varying interpretation of the RFA's requirements by federal agencies.[11]

Other statutory requirements also appear to have fallen short of proponents' expectations. For example, section 202 of the Unfunded Mandates Reform Act requires agencies to prepare "written statements" containing, among other things, estimates of future compliance costs and any disproportionate budgetary effects "if and to the extent that the agency in its sole discretion determines that accurate estimates are reasonably feasible and that such effect is relevant and material." The statute gives agencies the same discretion regarding estimates of the effects of their rules on the national economy. Therefore, an agency can avoid these estimates if, in its sole discretion, it considers them inaccurate, unfeasible, irrelevant, or immaterial. Likewise, section 203 of UMRA requires agencies to develop plans to involve small governments in the development of regulatory proposals that have a "significant or unique" effect on those entities. Therefore, an agency that concludes that a rule's effect on small governments will not be "significant" or "unique" can avoid this requirement. When GAO examined the implementation of UMRA in 1998, it concluded that the act had little effect on agency rulemaking, due largely to statutory exemptions.[12] The act did not cover most of the rules that GAO examined with a $100 million impact on the economy, and when a rule was covered, UMRA did not require the agency to do much more

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[9] U.S. General Accounting Office, *Regulatory Flexibility Act: Implementation in EPA Program Offices and Proposed Lead Rule*, GAO/GGD-00-193, Sept. 20, 2000.

[10] See *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001).

[11] See, for example, U.S. General Accounting Office, *Regulatory Flexibility Act: Agencies' Interpretations of Review Requirements Vary*, GAO/GGD-99-55, April 2, 1999; U.S. General Accounting Office, *Regulatory Flexibility Act: Implementation in EPA Program Offices and Proposed Lead Rule*, GAO/GGD-00-193. Sept. 20, 2000.

[12] U.S. General Accounting Office, *Unfunded Mandates: Reform Act Has Had Little Effect on Agencies' Rulemaking Actions*, GAO/GGD-98-30, Feb. 4, 1998.

than it was already required to do under other statutes and executive orders. GAO reached a similar conclusion in its 2004 examination of UMRA's implementation.[13] While critics deride this situation as regulatory reform ineffectiveness, others contend that Congress had good reason to entrust this amount of discretion to the agencies.

Some reforms have been related to or built on other reforms with some of the above-mentioned issues. For example, the "look back" requirements in section 610 of the RFA (mandating that agencies review certain rules within 10 years of their issuance) are triggered when the rulemaking agency determines that a rule has a "significant economic impact on a substantial number of small entities." As mentioned previously, some agencies certify almost all of their rules as not having that level of impact, so they can avoid section 610's requirements (as well as the analytic requirements in the RFA). For this and other reasons (e.g., a lack of clarity regarding key terms), studies of agencies' implementation of section 610 have consistently indicated that few of the required look-back reviews appear to be conducted.[14]

Section 212 of SBREFA requires agencies to publish one or more compliance guides for each rule or group of related rules for which the agency is required to prepare a final regulatory flexibility analysis under the RFA. Therefore, if the agency concludes that the final rule would not have a "significant" impact on a "substantial" number of small entities, the agency is not required to prepare a compliance guide. Agencies are given "sole discretion" in the use of plain language in the guides, and the statute does not indicate when the guides must be developed or how they must be published. Therefore, under section 212, an agency might develop a compliance guide years after a final rule is published with no input from small entities. In 2001, GAO reviewed agencies' implementation of section 212 and concluded that the requirement did not appear to have had much of an impact on agencies' rulemaking actions.[15]

Presidential Initiatives. In addition to these and other congressionally-established requirements, each President within the past 35 years has required some form of regulatory analysis before rules are published in the *Federal Register*. In addition to establishing OIRA review of rules, President Reagan's Executive Order 12291 generally required covered agencies to prepare a "regulatory impact analysis" for each "major" rule, which was defined as any regulation likely to result in (among other things) an annual effect on the economy of $100 million. Those analyses were required to contain a description of the potential benefits and costs of the rule, a description of alternative approaches that could achieve the regulatory goal at lower cost (and why they weren't selected), and a determination of the net benefits of the rule.

These analytical requirements remained in place until September 1993, when President Clinton issued Executive Order 12866. This executive order, which is still in effect,

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[13] U.S. General Accounting Office, *Unfunded Mandates: Analysis of Reform Act Coverage*, GAO-04-637, May 12, 2004.

[14] CRS Report RL32801, *Reexamining Rules: Section 610 of the Regulatory Flexibility Act*, by Curtis W. Copeland; General Accounting Office, *Regulatory Flexibility Act: Agencies Interpretations of Review Requirements Vary*, GAO/GGD-99-55, April 2, 1999.

[15] U.S. General Accounting Office, *Regulatory Reform: Compliance Guide Requirement Has Had Little Effect on Agency Practices*, GAO-02-172, Dec. 28, 2001.

established analytical requirements that are similar (although not identical) to those it replaced. For example, the order requires a cost-benefit analysis for all "economically significant" rules (essentially the same as "major" rules under Executive Order 12291) containing an assessment of the anticipated costs and benefits of the regulatory action and an assessment of the costs and benefits of alternatives to the regulatory action (with an explanation of why the planned action is preferable).

Researchers have examined agencies' economic analyses of rules under Executive Order 12866 and related guidance documents, and several of those studies indicated that the agencies' analyses are not always consistent with the requirements in the order or the guidance.[16] For example, in 1998 GAO reported that some of the 20 economic analyses that it examined did not discuss alternatives to the proposed regulatory action and, in many cases, it was not clear why the agencies used certain assumptions.[17] Five of the analyses did not discuss uncertainty associated with the agencies' estimates of benefits or costs or document the agencies' reasons for not doing so. GAO has also examined the cost-benefit analyses for particular rules, and often found them lacking in some of the same ways.[18] Other studies have criticized agencies for not providing quantitative information on net benefits in their analyses.[19] Still other studies have examined the accuracy of agencies' regulatory cost estimates, often concluding that costs are overestimated.[20] OMB reviewed the literature on *ex ante* cost and benefit estimates, and concluded that federal agencies tend to overestimate both benefits and costs.[21]

In addition to studies examining the implementation of cost-benefit and other rulemaking requirements, a large body of literature has developed debating the very notion of subjecting agencies' rules to these analytical requirements. Those supporting the use of these analytical methods view cost-benefit analysis as a helpful and neutral tool in regulatory

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[16] See, for example, Richard D. Morgenstern,ed., *Economic Analyses at EPA: Assessing Regulatory Impact* (Washington: Resources for the Future, 1997); and Robert W. Hahn, ed., *Risks, Costs, and Lives Saved: Getting Better Results from Regulation* (Washington: AEI Press, 1996).

[17] U.S. General Accounting Office, *Regulatory Reform: Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses*, GAO/RCED-98-142, May 26, 1998.

[18] U.S. Government Accountability Office, *Clean Air Act: Observations on EPA's Cost-Benefit Analysis of Its Mercury Control Options*, GAO-05-252, Feb. 28, 2005. GAO concluded that EPA did not, among other things, consistently analyze available options or provide estimates of the costs and benefits of each option.

[19] See, for example, Robert W. Hahn and Patrick Dudley, *How Well Does the Government Do Cost-Benefit Analysis?*, Working Paper 04-01 (Washington: AEI-Brookings Joint Center for Regulatory Studies, Jan. 2004).

[20] For a summary of this literature, see Winston Harrington, Richard D. Morgenstern, and Peter Nelson, "On the Accuracy of Regulatory Cost Estimates," *Journal of Policy Analysis and Management, vol. 19 (2000), pp. 297-322.* See also (former EPA Administrator) William K. Reilly, "The EPA's Cost Underruns, *Washington Post*, Oct. 14, 2003, p. A-23, which said "a review of some of the major regulatory initiatives overseen by the EPA since its creation in 1970 reveals a pattern of consistent, often substantial overestimates of their economic costs."

[21] U.S. Office of Management and Budget, Office of Information and Regulatory Affairs, *Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, pp. 41-52, available at [http://www.whitehouse.gov/omb/inforeg/2005_cb/final_2005_cb_report.pdf].

decisionmaking.[22] They contend that some type of cost-benefit balancing takes place during the rulemaking process anyway, and that the formal analysis simply makes that balancing (with the associated data and assumptions) more explicit, systematic, and rigorous. Furthermore, they argue that putting as accurate a dollar value on costs and benefits as possible makes decisions regarding whether and how to regulate easier and more rational. As one author stated, "[m]onetizing risk and environmental benefit does not devalue these outcomes, but rather gives them real economic value when the effects might otherwise be ignored."[23]

Others, however, assert that cost-benefit analysis is inherently flawed and biased against regulation.[24] For example, they assert that because regulatory benefits are generally more difficult to measure in dollar terms than regulatory costs, cost-benefit analysis is not carried out on a level playing field. Measurement of the benefits associated with health, safety, and environmental rules often requires an assessment of risk (e.g., how many people would get sick or die in the absence of the regulatory intervention) and a monetization of the associated benefits (i.e., placing a dollar value on the lives saved or illnesses prevented). These steps frequently involve significant methodological and ethical difficulties. Data are frequently not available to measure regulatory risks precisely, and using "willingness to pay" models to determine the values to assign to health effects is highly controversial. Critics of cost-benefit analysis also contend that regulatory cost data are often provided by regulated entities, who have an incentive to inflate those costs in order to influence agencies not to issue the rules. Other criticisms focus on the use of "discount rates" that reduce the value of future benefits to current dollars, and the "distributional" effects that are not often considered in such analyses. Finally, these critics suggest that although executive orders and statutes often indicate that non-monetized benefits must be considered as part of the rule development process, there is a natural tendency to discount or disregard non-monetized benefits. Still other critics assert that regardless of whether cost benefit analysis is neutral in concept, it is not neutral in effect, tending to result in the promulgation of fewer and weaker rules.[25]

Areas for Possible Further Research. In addition to the analytical requirements discussed above, a variety of other efforts have been made by Congress or Presidents to constrain agency rulemaking, including moratoriums on new rulemaking at the start of new presidential administrations, efforts to establish regulatory "accounting" mechanisms (which could pave the way to the establishment of a "regulatory budget"), the establishment of "advocacy review panels" at the start of certain EPA and OSHA rules, and attempts to limit the impact of rules on federalism and on individual privacy. After more than 25 years of experience with these various requirements, we know surprisingly little about their effectiveness or, where effectiveness is suspect, how they can be improved. Issues that Congress, ACUS, or both might explore in this area include the following:

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[22] See, for example, Cass R. Sunstein, *The Cost-Benefit State: The Future of Regulatory Protection* (Chicago: American Bar Association, 2002).

[23] W. Kip Viscusi, "Monetizing the Benefits of Risk and Environmental Regulation," *Fordham Urban Law Journal*, vol. 33 (May 2006, p. 1003.

[24] See, for example, Lisa Heinzerling and Frank Ackerman, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection* (Washington: Georgetown University, 2002).

[25] David M. Driesen, "Is Cost-Benefit Analysis Neutral?," *University of Colorado Law Review*, vol. 77 (Spring 2006), pp. 335-404.

- Is cost-benefit analysis inherently biased in that the benefits of health and safety rules are often difficult or impossible to monetize? If not, can steps be taken to ensure that regulatory costs and benefits are fairly and accurately measured?

- Does OMB apply the cost-benefit analysis requirements in Executive Order 12866 and use cost-benefit information in a consistent way? For example, does OMB require all rules to have a cost-benefit analysis, or are certain types of rules or rules from certain agencies (e.g., Homeland Security rules) essentially exempt from these requirements?

- How accurate are agencies' pre-promulgation estimates of regulatory costs and benefits? How much do cost-benefit studies cost? Do cost-benefit requirements pass a cost-benefit test?

- Should Congress or the Administration define key terms in the Regulatory Flexibility Act (e.g., "significant economic impact on a substantial number of small entities")?

- Should agency rules be reexamined periodically to ensure that they are still needed or impose the least burden? If so, who should have that reexamination responsibility?

- Should the myriad of analytical and accountability requirements in various statutes and executive orders be rationalized and codified in one place?

- Have the analytical and accountability requirements contributed to what is called the "ossification" of the rulemaking process?

Role of Science in Rulemaking

On May 9, 2006, the Center for the Study of Rulemaking at American University hosted an all-day conference for this Subcommittee entitled "The Role of Science in Rulemaking." As Neil Kerwin, interim president of American University and director of the Center for the Study of Rulemaking, said in his opening remarks, "rulemaking is the transformation of information into legal obligations and rights. That information takes many forms, but the type of information that contributes most profoundly to a vast swath of rulemaking can be broadly categorized as scientific."

The role of science in rulemaking has become highly controversial in recent years, with observers from both the left and the right of the political spectrum suggesting that "sound science" has been given insufficient weight in the development of regulatory standards. Some assert that closer adherence to science would lessen the burden of unnecessary regulation, thereby lowering regulatory costs. Others argue that science is often trumped by political considerations, and as a result regulatory standards that science suggests are needed do not get developed. As part of that debate, questions have been raised about the quality of data that are used in developing proposed and final rules, the use of peer review panels as part of the process to ensure quality, and the role that risk assessment can/should play in deciding what to regulate and at what levels.

Information Quality Act. The May 2006 symposium featured panels discussing such topics as the role of science advisory panels in the rulemaking process, science and the judicial review of rulemaking, and government agencies' science capabilities. The issues discussed by those panels were too numerous and varied to detail here, but included how advisory panels can be structured to ensure neutral competence and how the courts should treat agencies' science determinations. Another panel focused on OIRA's recent science-related initiatives, and those initiatives were a consistent theme in each of the panel discussions.

The starting point of those OIRA initiatives was an act of Congress — a two-paragraph provision added to the 700-page Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106-554) that is more commonly known as the "Data Quality Act" or the "Information Quality Act" (IQA) (codified at 44 U.S.C. 3504(d)(1) and 3516). Although little noticed at the time, the IQA has subsequently been the subject of intense debate and controversy. The act required OMB to issue guidance to federal agencies designed to ensure the "quality, objectivity, utility, and integrity" of information disseminated to the public. It also required agencies to issue their own information quality guidelines, and to establish administrative mechanisms that allow affected persons to seek correction of information maintained and disseminated by the agencies that does not comply with the OMB guidance.

Supporters of the IQA contended that it and the resultant OMB and agency guidelines would improve the quality of agency science and regulation and force agencies to regulate based on the best science available. Critics, on the other hand, said that the law was a tool by which regulated parties can slow and possibly stop new health, safety, and environmental standards, and that could lead to the revision or elimination of existing standards. They also contended that the act could have a chilling effect on agency distribution and use of scientific information.

In retrospect, it appears that both of these positions were overstated. OMB has reported that the expected flood of IQA correction requests did not occur (only 85 in the first two years of implementation), and that the correction request process had been used by virtually all sectors of society (albeit primarily by business groups). OMB said "to our knowledge, the (act) has not affected the pace or length of rulemakings," but neither it nor the agencies presented any data on this issue. Finally, OMB noted that most non-frivolous requests were denied because "a reasonable scientist could interpret the available information the way the agency had."[26]

Recent court decisions indicate that agency denials of information correction requests are not judicially reviewable. For example, on June 21, 2004, a U.S. district court ruled that such terms as "quality," "objectivity," "utility," and "integrity" are not defined in the IQA, and the history of the legislation does not provide any indication as to the scope of these terms. Therefore, absent any "'meaningful standard' against which to evaluate the agency's discretion, the Court finds that Congress did not intend the IQA to provide a private cause

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[26] Office of Management and Budget, *Draft Report to Congress on the Costs and Benefits of Federal Regulations*, p. 50, available at [http://www.whitehouse.gov/omb/inforeg/2005_cb/draft_2005_cb_report.pdf].

of action."[27] On November 15, 2004, the U.S. District Court for the Eastern District of Virginia (Alexandria Division) ruled that the Salt Institute and the Chamber of Commerce lacked standing to sue (e.g., they had suffered no "injury in fact"), and that judicial review of the agency's decisionmaking was not available. On March 6, 2006, the U.S. Court of Appeals for the Fourth Circuit dismissed the appeal by the Salt Institute and the Chamber of Commerce, agreeing with the district court that the appellants lacked standing because they did not suffer an injury from the published data.[28] The Fourth Circuit concluded that the IQA "creates no legal rights in any third parties," including any right to "information or to correctness." Therefore, the court argued, "appellants cannot establish injury in fact and, therefore, lack Article III standing to pursue their case in the federal courts."

At the May 2006 panel discussion on OMB's science-related initiatives, Bill Kovacs from the U.S. Chamber of Commerce said that, because of these recent court decisions, the IQA is "little more than a nice academic exercise," and that his organization planned to go back to Congress "to get judicial review provisions put into the law." In contrast, Rena Steinzor of the University of Maryland School of Law said that the IQA represented the "corpuscularization of science; that is, looking at each piece of scientific evidence very critically, deconstructing every study, questioning each individual piece as opposed to viewing all the scientific evidence together and making a scientific judgment on what the weight of the evidence tells us." Don Arbuckle, then acting administrator of OIRA, said that OMB believes that the act was "working quite well," and characterized the IQA and related guidelines as "more of an internal government quality control exercise than a regulation or a law that is challengeable through the judicial branch." He also said that the guidance places a "hefty data burden of proof on the petitioner," and was not intended to "give people an easy avenue to criticize government work."

Peer Review. Another science-related OIRA initiative has been the development of governmentwide standards for peer review of scientific information used in developing agency regulations. OIRA indicated that the bulletin was needed because agencies' peer review practices were inconsistent, and government-wide standards would make regulatory science more competent and credible. The initial proposed bulletin, published in September 2003, aroused substantial controversy, with some observers expressing concern that it could create a centralized peer review system within OMB that would be vulnerable to political manipulation or control by regulated entities.[29] OMB received nearly 200 comments on the proposal, including comments from Members of Congress, trade associations, public interest groups, and recognized experts in the field of peer review and scientific research. At our May 2006 symposium, Al Teich of the American Association for the Advancement of Science said that many scientists concluded that the initial bulletin appeared to be "a means of attacking regulation by attacking the science behind it."

As a result of these comments, OMB later published a "substantially revised" version of the bulletin that gave agencies more discretion to determine when information required a peer review, and when the more detailed review requirements for "highly influential"

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[27] *In re: Operation of the Missouri River Sys. Litig.*, No. 03-MD-1555 at 49 (D. Minn. June 21, 2004) (order granting motions for summary judgment).

[28] *Salt Institute; Chamber of Commerce of the United States of America v. Michael O. Leavitt, Secretary of Health and Human Services*, No. 05-1097, Mar. 6, 2006.

[29] Office of Management and Budget, Executive Office of the President, "Proposed Bulletin on Peer Review and Information Quality," 68 *Federal Register* 54023 (Sept. 15, 2003).

information were applicable. Also, unlike the proposed bulletin, the revised bulletin did not exclude individuals from being peer reviewers if they had received research grants from the agency disseminating the information being peer reviewed. The bulletin essentially requires agencies to (1) have a peer review conducted on all "influential scientific information" that the agency intends to disseminate, (2) have all "highly influential scientific assessments" peer reviewed according to more specific and demanding standards, and (3) indicate what "influential" and "highly influential" information the agency plans to peer review in the future. Although these revisions were generally embraced by the scientific community and others, business groups believed the changes had weakened the bulletin to such an extent that they withdrew their initial support. Still others believed the changes had not gone far enough, asserting that the bulletin was unnecessary and did not appropriately guard against appointment of reviewers with conflicts of interest.

On December 15, 2004, OMB published a final version of the peer review bulletin on its web site.[30] OMB said this version reflected "minor revisions" made in response the public comments on the revised bulletin. For example, the final bulletin requires agencies to disclose the names of peer reviewers to the public and adds an annual reporting requirement to allow OMB to track how agencies are using the bulletin. Agencies are still afforded substantial discretion to determine when and what type of peer review is required. The amount of discretion that agencies actually have in carrying out their peer review programs (or, conversely, the amount of control that OMB retains) will be apparent only through the bulletin's implementation, and therefore could vary substantially from one administration to another. Certain provisions of the peer review bulletin took effect in June 2005, with other provisions taking effect six months later.

To date, I am unaware of any empirical studies of how this peer review bulletin has been implemented. Nevertheless, the bulletin is likely to have a significant effect on federal rulemaking and other forms of information dissemination and public policy, both directly and indirectly through references to the bulletin by others. For example, section 402 of the "Specialty Crops Competitiveness Act of 2004" (Pub. Law 108-465, signed by the President on Dec. 21, 2004) indicated that a required peer review of the procedures and standards governing the consideration of certain import and export requests "shall be consistent with the guidance by the Office of Management and Budget pertaining to peer review and information quality."

Risk Assessment. On January 9, 2006, OIRA released a proposed bulletin on risk assessment for comment by the public and for peer review by the National Academy of Sciences (NAS).[31] The proposed bulletin would, if made final, establish general risk assessment and reporting standards, and establish special standards for "influential" risk assessments by all agencies. Risk assessment is defined in the bulletin as a document that "assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety, or the environment." In a regulatory context, risk assessment helps agencies identify issues of potential concern (e.g.,

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[30] Office of Management and Budget, *Final Information Quality Bulletin for Peer Review*, Dec. 15, 2004, available at [http://www.whitehouse.gov/omb/inforeg/peer2004/peer_bulletin.pdf].

[31] Office of Management and Budget, "Proposed Risk Assessment Bulletin," Jan. 9, 2006, available at [http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf].

whether exposure to a given risk agent causes effects such as cancer, reproductive and genetic abnormalities, or ecosystem damage); select regulatory options; and estimate a forthcoming regulation's benefits. OMB said that "there is general agreement that the risk assessment process can be improved, and said the purpose of the bulletin is "to enhance the technical quality and objectivity of risk assessments prepared by federal agencies by establishing uniform, minimum standards."

Although characterized as "guidance" in the document's summary, the narrative text mentions the "requirements" of the bulletin, and the language in the bulletin prior to the standards lists the standards with which "[e]ach agency shall" comply. However, OMB also says that the bulletin applies to all agency risk assessments "to the extent appropriate." Agency heads are authorized to waive or defer some or all of the requirements in the bulletin "where warranted by a compelling rationale." Public comments on the bulletin were requested by June 15, 2006, and on June 22, 2006, OMB posted the comments it had received on its web site.[32] Those comments varied significantly, with some suggesting ways to make the document stronger and more inclusive, while others suggested that OMB abandon the bulletin altogether.

On March 22, 2006, a committee of the Board on Environmental Issues and Toxicology within the National Academies' Division of Earth and Life Sciences began what is expected to be an 11-month peer review of OMB's proposed bulletin. On May 22, 2006, the committee held a public meeting on OMB's proposed risk assessment bulletin. According to press accounts, the nine federal agency officials who testified at the meeting voiced a variety of opinions about the bulletin.[33] For example, the Director of FDA's Center for Drug Evaluation and Research reportedly said that if the bulletin was made final in its current form, doctors and the public might not receive timely warnings about potential health risks posed by drugs and medical devices (e.g., warnings related to the use of the anti-inflammatory drug Vioxx). He and two other agency officials (from the National Institute of Environmental Health Sciences and the National Institute for Occupational Safety and Health's Risk Evaluation Branch) reportedly said that the bulletin's definition of risk assessment is so broad that many types of federal analyses could be inappropriately covered by its requirements. On the other hand, EPA's science advisor was quoted as saying that the agency was in "pretty good shape" in terms of meeting the requirements in the proposed bulletin, but nevertheless suggested that the guidance be revised to explain how much flexibility agencies have regarding its requirements (e.g., how agencies can get waivers from the bulletin's requirements).

Like the peer review bulletin, the manner in which OMB implements the risk assessment bulletin will determine its effectiveness. For example, it is unclear the extent to which agencies will be allowed to waive or defer the bulletin's requirements when they believe it is "warranted by a compelling rationale." Similarly, it is unclear whether OMB will allow agencies to decide when a risk assessment is "influential" (thereby triggering additional standards in the bulletin) and whether OMB will treat the bulletin's provisions as "guidance" or as "requirements."

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[32] See [http://www.whitehouse.gov/omb/inforeg/comments_rab/list_rab2006.html].

[33] Pat Phibbs, "Definition of Risk Assessment Deemed Too Broad by Several Health Agency Officials," *BNA Daily Report for Executives*, May 23, 2006, p. A-15.

Possible Issues for Congressional or ACUS Consideration. As the above discussion suggests, a number of issues remain for possible congressional consideration, or for further study by a re-funded ACUS or some other body. In some cases, Congress could weigh in and resolve the issue. For example, in light of recent court decisions, if Congress wanted agencies' decisions under the Information Quality Act to be judicially reviewed, it could resolve any lingering questions by amending the statutes and permitting judicial review. Likewise, if Congress objected to using risk standards for one statute and applying them to other statutes, it could act through legislation or through oversight of OMB's risk assessment bulletin.

Among the questions that may merit further study are the following:

- How can scientific advisory panels be constructed to ensure that they are unbiased?

- Under what circumstances should agencies' regulatory policies deviate from the recommendations of their scientific staff and advisory bodies?

- What were Congress's intentions in passing the IQA? Has it served those purposes?

- Do agencies have too much discretion to deny correction requests under the IQA? What effect has the act had on the length of time it takes agencies to issue rules? What if anything should be done to ensure that the act is consistently implemented?

- Should OMB take a more active role in reviewing agencies' decisions under the IQA? Should Congress or OMB initiate the collection of data regarding the IQA's effect on rulemaking or agencies' resources?

- What is the appropriate role of the courts in reviewing science-based agency regulatory decisions?

- Are governmentwide standards for peer review and risk assessment needed? Does OMB have the authority to issue such standards? What effect have these requirements had on the length of time it takes agencies to issue rules?

- Are agencies complying with the peer review and risk assessment bulletins? For example, are agencies posting agendas listing their upcoming peer reviews? Are agencies peer reviewing all "influential" information? Are some agencies complying better than others? Should Congress refer to these bulletins in legislation as models for particular peer reviews or risk assessments?

- What constitutes the "weight of the evidence" in making risk-based regulatory decisions? Should Congress define the term, or should it be left up to the agencies within a specific regulatory context?

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Mr. Chairman, that concludes my prepared statement. I would be happy to answer any questions that you or other Members of the Subcommittee might have.